

Mediterranean Wellness Data

Background: Mediterranean Wellness currently delivers a structured eight week curriculum on a nationwide level for corporations (ex. Westinghouse and Alcoa), insurance companies (ex. HealthAmerica, Highmark BCBS) and school districts (ex. Pittsburgh area schools). The program is based on the traditional Mediterranean diet of food selection and behavioral eating habits.

Results in the corporate wellness environment have demonstrated the control of glucose in type 1 diabetes (T1D) (Figure 1), as well as the reduction of cholesterol (Figure 3).

To follow up on these preliminary data, Mediterranean Wellness has worked in association with two medical research institutions; the Diabetes Research Institute at the University in Miami, Florida (Figure 2), and the Vail Valley Medical Center in Vail, Colorado (Figure 3).

Examples from a detailed case study: These data were obtained from a 33 year old female with severely uncontrolled T1D, who participated in the Mediterranean Wellness curriculum as a part of a corporate wellness initiative at ALCOA, Inc in Pittsburgh, PA. Glucose readings were provided at regular intervals, 5-6 times daily, with an electronic glucose monitor.

Glucose Control: This subject presented with dramatically uncontrolled glucose: mean 309.94 mg/dl, with a mean amplitude of glycemic excursion of ± 108 mg/dl. Daily glucose readings are shown in Figure 1 for the 6 weeks prior to the initiation of the protocol.

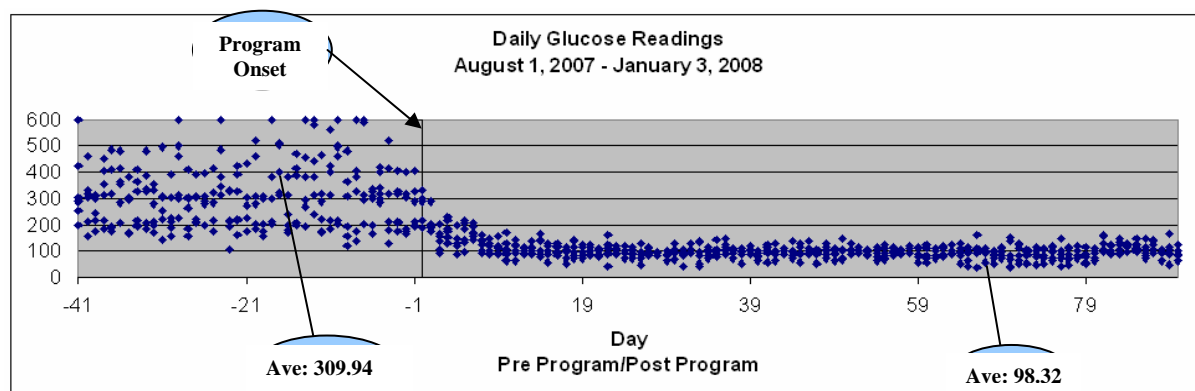


Figure 1. Glucose readings taken five times daily in Detailed Case Study. Vertical line aligned with program

The vertical line represents the onset of the curriculum. The patient's glucose record documents a substantial and rapid reduction in mean glucose to 98 mg/dl by week 8 of the intervention,

along with a decrease in the mean amplitude of glycemic excursion to ± 29 mg/dl.

To date, these results have been sustained (now well over 18 months, post-program).

A1C: Glycosylated hemoglobin levels were acquired at program initiation, after 6 weeks, 10 weeks, 18 weeks and again at 18 months. Each sampling showed a decrease in A1C, with the cumulative effect of reducing the A1C by a full half (10.0, 8.4, 8.2, 6.2, and 5.0, respectively, all units in mg/dl).

Cost Savings: Detailed hospitalization and medical expense records were provided by the subject. In the year prior to participating in the program, this subject was hospitalized for diabetic ketoacidosis (DKA) 4 times. The uncontrolled nature of the condition required monthly endocrinologist visits with extensive testing. Insulin usage was typically 4 vials per month, or \$4,320 per year.

Table 1: Cost Savings Analysis

Costs	Hospital	Insulin	Endocrinologist	Total
Pre	\$40,000	\$4,320	\$14,200	\$58,520
Post	\$0	\$2,160	\$2,400	\$4,560

Post-program insulin costs were reduced by half. The requirement to visit the endocrinologist has been reduced from 12 to 2 times/year. The patient has not required hospitalization since program onset. The net annual savings was ~\$53,000 on this single individual. By comparison, the cost of the Mediterranean Wellness curriculum is \$200.

Follow up assessment: T1D patients of the Diabetes Research Institute (DRI) completed the Mediterranean Wellness curriculum. These individuals met for each of the 8 weekly program lectures at the DRI. Participants also had access to a website platform, in which they could view recordings of each session as many times as they wished. Thus, participants could “attend” the lectures either directly or remotely via recordings.

Data Acquisition: All participants were fitted with a continuous glucose monitor for 3 days before, and 3 days after the program. Glucose levels were recorded in an ongoing fashion, and analyzed according to whether they were Above Normal Range (>180 mg/dl), Below Normal Range (<70 mg/dl), or Within Normal Range (70 – 180 mg/dl). These values were expressed as a percentage of the total time of data collection. Weight in pounds and A1C values were collected before and after the trial.

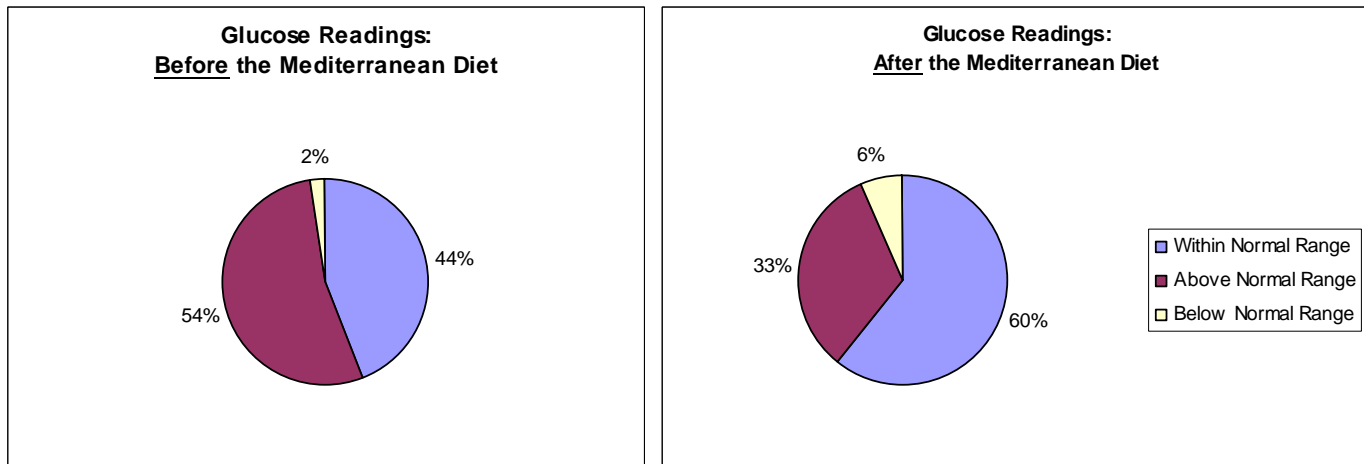


Figure 2. Continuous Glucose Monitor readings taken over 3 days Pre-program, and 3 days Post-program.

Results: Values are expressed as averages of the total. The average time of glucose excursions Above Normal Range significantly decreased, from 54% to 33% ($p < 0.03$). The average time of glucose excursions Within Normal Range significantly increased, from 44% to 60% ($p < 0.02$). The average time of glucose excursions Below Normal Range increased, although not significantly ($p < 0.08$). Weight and A1C both decreased over 8 weeks, although neither reached significance. A1C: Pre=7.8, Post=7.4. Weight: Pre=195, Post=189.

Cholesterol Control: Heart disease is the most prominent cause of death resulting from uncontrolled diabetes. The control of markers for heart disease is of special concern in these cases.

The detailed case study showed a total cholesterol decrease of 20 points (initial 210; final 190 mg/dl), over the course of the curriculum protocol (Figure 3).

Similarly, 46 hospital professionals at the Vail Valley Medical Center in Vail, CO participated in the Mediterranean Wellness curriculum. Total cholesterol was obtained before and after the program. After controlling for individuals who were taking adjunct medications, the program resulted in an average reduction in total cholesterol of 13.3 points per participant over 8 weeks ($p < 0.05$).

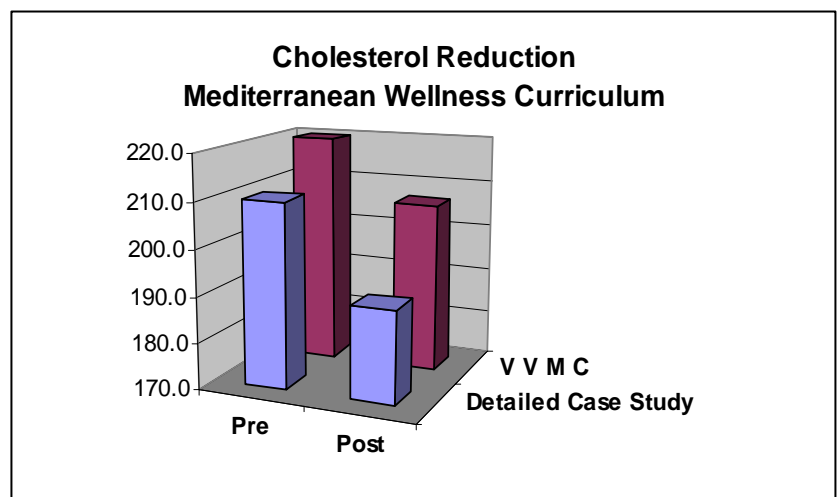


Figure 3. Cholesterol reductions without adjunct medication, result from the Mediterranean Wellness Curriculum

an average reduction in total cholesterol of 13.3 points per participant over 8 weeks ($p < 0.05$).

Discussion:

Taken together, these data show that this protocol could be used as an effective behavioral approach for controlling T1D co-morbidities. Moreover, the web-based delivery model is a cost-effective means to reach traditional patient groups as well as underserved rural areas.

The lower cholesterol found in the detailed case study and in the Vail Medical Center group, suggest that this risk factor may also be mitigated through a Mediterranean dietary and behavioral approach. The cost savings of reduced medication and hospitalization, coupled with the reach potential of the delivery model, offer strong commercial potential.